

Appln. No. 09/241,595
Amd. dated May 27, 2004
Reply to Office Action of January 28, 2004

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1 (Currently amended). A method of stimulating or enhancing a CTL response to a biologically active molecule in a mammalian subject in need of CTL response stimulation and enhancement, comprising administering to said subject by injection into the body of said subject, in a manner so as to elicit a CTL response, an effective amount of a composition comprising a- the biologically active molecule, either entrapped within the interior of an HBsAg particle or exposed or present at the surface of an HBsAg particle, wherein said biologically active molecule is not ~~covalently modified or~~ covalently attached to said HBsAg particle, and wherein said CTL response is enhanced relative to that produced by the biologically active molecule alone.

2-3 (Canceled).

4 (Previously Presented). The method of claim 1, wherein said biologically active molecule, when administered without said HBsAg particle, is substantially ineffective in producing a CTL response in said subject.

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5 (Original). The method of claim 1, wherein said HBsAg particle is a recombinant HBsAg particle derived from a mammalian cell.

6 (Previously Presented). The method of claim 1, wherein said biologically active molecule is an antigenic protein or peptide.

7 (Previously Presented). The method of claim 6, wherein said antigenic molecule is HIVenv/V3 peptide.

8 (Previously Presented). The method of claim 1, wherein said composition further comprises an immunostimulating molecule entrapped within or exposed or present at the surface of said HBsAg particle.

9 (Previously Presented). The method of claim 8, wherein said immunostimulating molecule is a cytokine.

10 (Previously Presented). The method of claim 8, wherein said immunostimulating molecule is an immunostimulatory oligonucleotide.

11 (Currently amended). A method of stimulating or modulating a CTL response to HBsAg in a mammalian subject in need of CTL response stimulation or modulation, comprising administering to said subject by injection into the body of said subject, in a manner so as to elicit a CTL response, an effective amount of a composition comprising an immunostimulating molecule either entrapped within the interior of an HBsAg particle or

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exposed or present at the surface of an HBsAg particle, wherein said immunostimulating molecule is not ~~covalently modified or~~ covalently attached to said HBsAg particle, and wherein said subject is a nonresponder at the CTL level when administered HBsAg particles without said immunostimulating molecule.

12-13 (Canceled).

14 (Original). The method of claim 11, wherein said immunostimulating molecule is a cytokine.

15 (Original). The method of claim 11, wherein said immunostimulating molecule is cholera toxin (CT) protein or staphylococcal enterotoxin B (SEB) protein.

16 (Previously Presented). The method of claim 11, wherein said immunostimulating molecule is an immunostimulatory oligonucleotide.

17 (Currently amended). A composition comprising an HBsAg particle, ~~and~~ a biologically active molecule either entrapped within the interior of an HBsAg particle or exposed or present at the surface of an HBsAg particle, and an immunostimulating molecule either entrapped within the interior of said HBsAg particle or exposed or present at the surface of said HBsAg particle, wherein said biologically active molecule is not ~~covalently modified or~~ covalently attached to said HBsAg particle.

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18 (Currently Amended). The composition of claim 17, wherein said biologically active molecule is an antigen.

19 (Currently Amended). The composition of claim 18, wherein said biologically active molecule is HIVenv/K^d peptide.

20-21 (Canceled).

22 (Currently Amended). The composition of claim ~~21~~ 17, wherein said immunostimulating molecule is a cytokine.

23 (Currently Amended). The composition of claim ~~21~~ 17, wherein said immunostimulating molecule is an immunostimulatory oligonucleotide.

24 (Currently Amended). The composition of claim ~~21~~ 17, wherein said immunostimulating molecule is cholera toxin (CT) protein or staphylococcal enterotoxin B (SEB) protein.

25 (Original). The composition of claim 17, further comprising a glycolipid incorporated into the exterior surface of the lipid bilayer of said HBsAg particle.

26 (Currently Amended). The composition of claim 17, wherein said composition is prepared by incubating said particle in an aqueous medium in the presence of said biologically active molecule and said immunostimulating molecule.

27 (Currently Amended). A method of incorporating a biologically active molecule into an HBsAg particle, comprising a step of incubating said particle at between about 35° C and about 60° C in an aqueous medium in the presence of said molecule.

28 (Canceled).

29 (Currently Amended). The method of claim 27, further comprising a step of incorporating a glycolipid into the exterior surface of said HBsAg particle.

30 (Previously Presented). The method of claim 29, wherein said incorporating step comprises co-incubating said glycolipid with said HBsAg particles and said biologically active molecule.

31 (Currently Amended). In a method of generating a CTL response to an antigenic molecule in a mammalian subject in need of CTL response generation, comprising administering by injection into the body of said subject, in a manner so as to elicit a CTL response, an effective amount of a composition which comprises an antigenic molecule, the improvement whereby the CTL response is enhanced, wherein said antigenic molecule is either entrapped within the interior of an HBsAg particle or exposed or present at the surface of an HBsAg particle, said antigenic molecule being not ~~covalently modified or~~ covalently attached to said HBsAg particle.

32 (Previously Presented). The method of claim 1, wherein said biologically active molecule is antigenic.

33 (Previously Presented). The method of claim 1, wherein said injection is selected from the group consisting of

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intraperitoneal, subcutaneous, intravenous, and intramuscular injection.

34 (Previously Presented). The method of claim 11, wherein said injection is selected from the group consisting of intraperitoneal, subcutaneous, intravenous, and intramuscular injection.

35 (Previously Presented). The composition of claim 17, wherein said biologically active molecule is antigenic.

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